REMARKS

Claims 1, 2, 7, 8, 10-18, 20 and 21 are pending in the instant application. Applicants have hereinabove cancelled claims 2 and 16-18 without prejudice or disclaimer to their right to pursue the subject matter of these claims in a future application. In addition, applicants have hereinabove amended claims 1, 7, 8, 10 and 11-15. Support for the amendments to the claims may be found, *inter alia*, in the subject specification as follows: claims 1 and 11-15: original claim 2; and claim 22: original claim 2. The remaining changes to the claims merely introduce minor grammatical and format changes. This Amendment does not involve any issue of new matter. Therefore, entry of this Amendment is respectfully requested such that claims 1, 7, 8, 10-15 and 20-21 will be pending and under examination.

Claim Rejections Under 35 U.S.C. §103(a)

Block et al. (WO 00/27382)

The Examiner rejected claim 18 under 35 U.S.C. 103(a) as allegedly being unpatentable over Block et al. (WO 00/27382). The Examiner alleges that it would have been obvious to one of ordinary skill in the art at the time of the invention to treat Parkinson's disease in a patient comprising the administration to said patient a therapeutically effective rofecoxib using the guidance of Block et al. The Examiner alleges that one of ordinary skill in the art would have a reasonable expectation of success in doing so because the prior art as a whole teaches treating Parkinson's disease with rofecoxib. The Examiner alleges that the invention would have been prima facie obvious to one skilled in the art at the time it was made.

In response, applicants have hereinabove cancelled claim 18 without prejudice or disclaimer. Therefore, the rejection thereof is now moot. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Block et al. (WO 00/27382) in view of Shapiro (US 5,668,117)

The Examiner rejected claims 1, 2, 7, 8, 10-17, 20 and 21 under 35 U.S.C. 103(a) as alleged being unpatentable over Block et al. (WO 00/27382) in view of Shapiro (US 5,668,117). The Examiner alleges that it would have been obvious to one of ordinary skill in the art to treat Parkinson's disease by administering therapeutically effective amounts of (1) rofecoxib as taught by Block et al. in combination with (2) pergolide and/or (3) selegiline as taught by Shapiro et al. The Examiner stated

that one of skill in the art would have been motivated to combine these components to treat Parkinson's disease because they are individually taught in the art to treat Parkinson's disease. The Examiner alleged that it would have been obvious to combine individual compositions taught to have the same utility to form a new composition for the same purpose.

In response, applicants have hereinabove cancelled claims 2, 16 and17 without prejudice or disclaimer. Therefore, the rejection thereof is now moot.

In response to the Examiner's rejection of the remaining claims, applicants respectfully traverse, and maintain that a prima facie case of obviousness does not exist with respect to any of the pending claims.

Claims 1, 7, 8, 10-15, 20 and 21 provide methods for treating or relieving the symptoms of Parkinson's disease in a patient in need thereof comprising administering to said patient a combination of a COX-2 inhibitor and an antiparkinson agent selected from the group consisting of an anticholinergic agent, a dopaminergic agent, a monoamine oxidase agent and amantadine, in therapeutically effective amounts. In preferred embodiments, the COX-2 inhibitor is rofecoxib and the antiparkinson agents are pergolide and selegiline.

To establish a prima facie case of obviousness, the Examiner must demonstrate three things with respect to the claim. First, the cited references, when combined, must teach or suggest every limitation of the claim. Second, one of ordinary skill would have been motivated to combine the teachings of the cited references at the time of the invention. And third, there would have been a reasonable expectation that the claimed invention would succeed.

Here, the cited references fail to support a prima facie case of obviousness. Specifically, Block et al. when combined with Shapiro, fail to provide a motive to combine and a reasonable expectation of success.

Block et al. does not teach or suggest a combination of a COX-2 inhibitor and an antiparkinson agent selected from the group consisting of an anticholinergic agent, a dopaminergic agent, a monoamine oxidase agent and amantadine, to treat or ameliorate the symptoms of Parkinson's disease. Instead, Block et al. suggest that the combination of a GABA-A alpha5 inverse agonist and a COX-2 inhibitor might treat Parkinson's disease.

Likewise, Shapiro does not teach or suggest a combination of a COX-2 inhibitor and an antiparkinson agent selected from the group consisting of an anticholinergic agent, a dopaminergic agent, a monoamine oxidase agent and amantadine, to treat or ameliorate the symptoms of Parkinson's disease. Nowhere does Shapiro mention the use of a COX-2 inhibitor to be used in combination with an antiparkinson agent to treat Parkinson's disease.

According to the MPEP 2143.01,

> "[t]he mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination."

In re Mills, 916 F.2d 680 (Fed. Cir. 1990) (emphasis added). As demonstrated above, there is simply no motivation or suggestion to combine the cited references to create applicants' claimed invention. The collection of cited references is the result of the Examiner's impermissible use of hindsight to combine these references based on knowledge of applicants' invention and underlying discovery. None of the references cited by the Examiner give any suggestion, motivation or "indication of which parameters [are] critical or [a] direction as to which of many possible choices is likely to be successful" to one skilled in the art to use a COX-2 inhibitor and an antiparkinson agent selected from the group consisting of an anticholinergic agent, a dopaminergic agent, a monoamine oxidase agent and amantadine, to treat or ameliorate the symptoms of Parkinson's disease. (*In re O'Farrell*, 853 F.2d 894, 903 (Fed Cir. 1988). Essentially, one skilled in the art would have had to conduct undue experimentation to achieve applicants' successful yet unexpected result. Devoid of any support to the contrary, an "invitation to try," which applicants do not concede exists, is considered inadequate support for an obviousness rejection. (*O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988)).

In view of the above remarks, applicants maintain that claims 1, 7, 8, 10-15, 20 and 21 satisfy the requirements of 35 U.S.C. 103(a). Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.